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EXAMINER
BRITTINGHAM, D

33M1/0608

ART UNIT PAPER NUMBER

C. G. MERSEREAU
HAUGEN AND NIKOLAI
820 INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH
MINNEAPOLIS, MN 55402-3325

3308

DATE MAILED: 06/08/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

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This application has been examined Responsive to communication filed on 3/3/94 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION

1. Claims 70 - 100 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims 70 - 100 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

EXAMINER'S ACTION

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Claim Rejections - 35 USC § 112

1. Claims 70-76 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims incorrectly depend from cancelled claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 77,80,93,99 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Berg, et al.

Berg discloses an injectable particulate implantation system comprising generally soft elastic particles dispersed in non-retentive physiological medium. The particles having rough surface texture forming surface irregularities. While Berg, et al does not specifically state that the microporous collagen beads are elastic or soft, it is well established in the art that

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collagen is generally malleable and somewhat resilient especially when compared to metallic or ceramic particles. Examiner contends that the inherent properties of collagen fall within the range of "generally soft, malleable and elastic" as broadly claimed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. Claims 78,79,81-89,91,94,96 and 97 are rejected under 35 U.S.C. § 103 as being unpatentable over Berg, et al .

Berg, et al discloses every features of the invention as claimed except for the specific range of the surface irregularities. Examiner makes the argument that, inherently, the microporous surface of Berg,et al must fall within the range as broadly claimed. Since the range of particles size has been disclosed as being from 50-350 microns, then it would follow that the pore size would have to be smaller than the particles size. The particles of Berg,et

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al meets all of the claimed structural limitations and therefor it would follow that the functional limitations would be inherently met.

Claims 82,83,84 see column 4, lines 55+.

Claims 85-89 see column 4, lines 45-68.

Claims 91,94,96,97 see column 2, lines 20-25 and column 3, lines 10-25.

6. Claim 98 is rejected under 35 U.S.C. § 103 as being unpatentable over Berg, et al further in view of Miyata, et al.

While it is not clear if the microporous collagen particles of Berg,et al is spherical, Miyata, et al shows an alternative method for forming porous collagen particles into spherical bodies. Though the particles of Miyata are not used in the fashion of that of Berg, it would have been obvious to one with ordinary skill in the art to utilize the teachings and technology of Miyata, et al in order to form a spherical body depending on surgical considerations.

7. Claims 81,90,92,95 and 100 are rejected under 35 U.S.C. § 103 as being unpatentable over Bucalo or Dupont (Publication: Nen-trac Microspheres).

Each of Bucalo and Dupont disclose polymer microspherical particles in a physiological vehicle. The references donot disclose any degree of surface roughness. Examiner maintains that the surface roughness inherently falls within the range as disclosed by applicant i.e. 10 angstroms -500 microns. It is well established in the art that a surface roughness of 5 microns or less is considered to be a highly smooth mirrored finish. Since

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neither of Bucalo or Dupont specifically recite surface roughness, Examiner maintains that these particles, if construed to be smooth, would inherently fall within in the broad range as disclosed by applicant

Response to Amendment

8. Applicant's arguments with respect to claim s 70-100 have been considered but are deemed to be moot in view of the new grounds of rejection.

Applicant has sufficiently changed the scope of the claims and has argued soft tissue augmentation as opposed to bone tissue. This argument is well taken, however the newly applied references are directed to soft tissue repair.

Conclusion

9. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL

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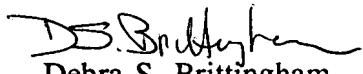
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EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Debra S. Brittingham whose telephone number is (703) 308-0858.



DAVID J ISABELLA
PRIMARY EXAMINER



Debra S. Brittingham
Examiner AU 3308
May 31, 1994